Precigen Provides Pipeline and Corporate Updates at the 40th Annual J.P. Morgan Healthcare Conference

Jan 12, 2022

- Company accomplished clinical milestones set for 2021 -
- Phase 2 trial planned for PRGN-2009 in combination with an anti-PD-1 checkpoint inhibitor in advanced human papillomavirus (HPV)-associated cancer-
- Multicenter expansion cohort planned for PRGN-3006 in acute myeloid leukemia and PRGN-3005 in ovarian cancer -
- Company to seek US Food and Drug Administration (FDA) guidance on rapid regulatory strategy for PRGN-2012 and PRGN-2009 given efficacy signals and significant unmet patient need -

GERMANTOWN, Md., Jan. 12, 2022 /PRNewswire/ -- Precigen, Inc. (Nasdaq: PGEN), a biopharmaceutical company specializing in the development of innovative gene and cell therapies to improve the lives of patients, today presented pipeline and corporate updates at the 40th Annual J.P. Morgan Healthcare Conference. Helen Sabzevari, PhD, President and CEO of Precigen, presented a summary of 2021 achievements and set forth Precigen's goals for 2022.

Precigen's presentation included the following pipeline announcements:

PRGN-3006 UltraCAR-T in Acute Myeloid Leukemia (AML)

- **Overview:** PRGN-3006 is an investigational multigenic, autologous chimeric antigen receptor T cell (CAR-T) therapy engineered to simultaneously express a CAR specifically targeting CD33, membrane bound IL-15 (mbIL15), and a kill switch. PRGN-3006 UltraCAR-T is under evaluation in a Phase 1/1b clinical trial for the treatment of patients with relapsed or refractory AML or higher-risk myelodysplastic syndromes (MDS). Trial subjects receive the PRGN-3006 infusion either without prior lymphodepletion (Cohort 1) or following lymphodepleting chemotherapy (Cohort 2). PRGN-3006 UltraCAR-T has been granted Orphan Drug Designation in patients with AML by the FDA.
- **Program Updates:** Precigen announced enrollment completion for Dose Level 3 of the lymphodepletion cohort. Interim data for patients treated in Dose Levels 1-3 of the non-lymphodepletion cohort and Dose Levels 1-2 of the lymphodepletion cohort were recently presented at the 63rd American Society of Hematology (ASH) Annual Meeting and Exposition. The dose escalation phase of the study is now complete for both the lymphodepletion and non-lymphodepletion cohorts and the Company plans to initiate a multicenter expansion phase of the study at Dose Level 3 with lymphodepletion in the first half of 2022. The Company plans to incorporate a repeat dosing regimen in the expansion phase. Additional Phase 1/1b data is expected in 2022.

PRGN-3005 UltraCAR-T in Ovarian Cancer

- **Overview:** PRGN-3005 UltraCAR-T is an investigational multigenic, autologous CAR-T cell therapy engineered to express a CAR specifically targeting the unshed portion of MUC16, which is highly expressed on ovarian tumors with limited normal tissue expression, mbIL15, and a kill switch. PRGN-3005 UltraCAR-T is under evaluation in a Phase 1/1b clinical trial for

the treatment of patients with advanced, recurrent platinum-resistant ovarian cancer. Trial subjects receive PRGN-3005 either via intraperitoneal (IP) (Arm A) or intravenous (IV) (Arm B) infusion.

- **Program Updates:** Precigen announced enrollment completion for Dose Level 3 of the IV arm, completing enrollment in both the IP and IV arms in the dose escalation phase of the study. Interim data for patients treated in Dose Levels 1-3 of the IP arm were recently presented at the Company's 2021 R&D Virtual Event. The Company has received FDA clearance to incorporate lymphodepletion at Dose Level 3 of the IV arm and will initiate the multicenter expansion phase of the study, incorporating redosing.

PRGN-3007 Next Generation UltraCAR-T with Intrinsic PD-1 Inhibition

- **Overview:** PRGN-3007, based on the next generation of the UltraCAR-T platform, is an investigational multigenic, autologous CAR-T cell therapy engineered to simultaneously express a CAR targeting receptor tyrosine kinase-like orphan receptor 1 (ROR1), mbIL15, a kill switch, and a novel mechanism for the intrinsic blockade of PD-1 gene expression. ROR1 is aberrantly expressed in multiple hematological tumors, including chronic lymphocytic leukemia (CLL), mantle cell leukemia (MCL), acute lymphoblastic leukemia (ALL), and diffuse large B-cell lymphoma (DLBCL) and solid tumors, including breast adenocarcinomas such as triple negative breast cancer (TNBC), pancreatic cancer, ovarian cancer, and lung adenocarcinoma. ROR1 is minimally expressed in healthy adult tissues.
- **Program Updates:** Precigen plans to initiate dosing in the Phase 1 study in ROR1+ hematological (CLL, MCL, ALL, DLBCL) and solid (TNBC) tumors in 2022.

PRGN-2012 AdenoVerse ™ Immunotherapy in Recurrent Respiratory Papillomatosis (RRP)

- **Overview:** PRGN-2012 is an investigational off-the-shelf (OTS) AdenoVerse immunotherapy designed to elicit immune responses directed against cells infected with HPV 6 or HPV 11 for treatment of RRP. PRGN-2012 is currently under evaluation in a Phase 1 clinical trial under a Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute (NCI). The Phase 1 trial is designed to follow 3+3 dose escalation of PRGN-2012 as an adjuvant immunotherapy following standard-of-care surgical removal of visible papillomas in adult patients with RRP. PRGN-2012 has been granted Orphan Drug Designation in patients with RRP by the FDA.
- **Program Updates:** Precigen announced enrollment completion for the Phase 1 dose escalation and expansion cohorts of the Phase 1 study. Interim data for the Phase 1 study were recently presented at the Company's 2021 R&D Virtual Event. The Company plans to seek FDA guidance on a rapid regulatory strategy for PRGN-2012 in RRP given the positive interim results and significant unmet patient need. Additional Phase 1 expansion data is expected in the second half of 2022.

PRGN-2009 AdenoVerse Immunotherapy in HPV-associated Cancers

- **Overview:** PRGN-2009 is an OTS investigational immunotherapy utilizing the AdenoVerse platform designed to activate the immune system to recognize and target HPV-positive (HPV+) solid tumors. PRGN-2009 is currently under evaluation in a Phase 1/2 clinical trial under a CRADA with the NCI. The Phase 1 trial is evaluating safety and response of PRGN-2009 as a monotherapy (Arm A) and in combination with M7824 (Arm B) in previously treated patients with recurrent or metastatic HPV-associated cancers.
- **Program Updates:** Precigen announced enrollment completion in the Phase 1 monotherapy arm. Enrollment is ongoing in the Phase 1 combination arm and the Phase 2 monotherapy arm in newly diagnosed OPSCC patients. Interim data for patients in the Phase 1 monotherapy and combination arms treated at Dose Levels 1-2 were recently presented at the Company's 2021 R&D Virtual Event. Additional Phase 1 data for both arms is expected in 2022. The Company plans to seek FDA guidance on a rapid regulatory strategy for PRGN-2009 given the positive interim results and significant unmet patient need. The Company also plans to initiate a Phase 2 study in advanced HPV-associated cancer indications in combination with an approved anti-PD-1 checkpoint inhibitor.

AG019 ActoBiotics ™

- **Overview:** AG019 is an investigational therapy designed to induce oral immune tolerance to reverse type 1 diabetes (T1D) and is currently under clinical evaluation for the treatment of early-onset T1D.The Phase 1b/2a clinical trial is evaluating AG019 as a monotherapy and in combination with teplizumab (PRV-031), which is currently under investigation in the PROTECT Phase 3 study for the treatment of newly diagnosed T1D.
- **Program Updates:** Precigen announced the completion of the Phase 1b/2a clinical trial. Positive results from the trial were presented last year at the Federation of Clinical Immunology Societies (FOCIS) Virtual Annual Meeting and European Association for the Study of Diabetes (EASD) 57th Annual Meeting. The Company plans to initiate discussions with the FDA and European Medicines Agency (EMA) for Phase 2/3 clinical trial design for AG019 in T1D.

"Precigen made significant clinical progress in 2021 across our pipeline programs. We were able to meet the major clinical goals we outlined at JPM last year, and exceeded some goals such as the rapid progress made for PRGN-2012 in RRP. Interim data presented in 2021 across three platforms – UltraCAR-T, AdenoVerse, ActoBiotics – and five clinical programs continue to produce positive results" said Helen Sabzevari, PhD, President and CEO of Precigen, "In 2022, we will continue to advance our clinical programs with a concentration on rapid paths to licensure for programs addressing

high unmet patient needs."

Precigen's J.P. Morgan presentation is available on the Company website in the Events & Presentations section at investors.precigen.com/events-presentations.

Precigen: Advancing Medicine with Precision ™
Precigen (Nasdaq: PGEN) is a dedicated discovery and clinical stage biopharmaceutical company advancing the next generation of gene and cell therapies using precision technology to target the most urgent and intractable diseases in our core therapeutic areas of immuno-oncology, autoimmune disorders, and infectious diseases. Our technologies enable us to find innovative solutions for affordable biotherapeutics in a controlled manner. Precigen operates as an innovation engine progressing a preclinical and clinical pipeline of well-differentiated therapies toward clinical proof-of-concept and commercialization. For more information about Precigen, visit www.precigen.com or follow us on Twitter @Precigen, LinkedIn or YouTube.

UltraCAR-T®
UltraCAR-T is a multigenic autologous CAR-T platform that utilizes Precigen's advanced non-viral *Sleeping Beauty* system to simultaneously express an antigen-specific CAR to specifically target tumor cells, mbIL15 for enhanced *in vivo* expansion and persistence, and a kill switch to conditionally eliminate CAR-T cells for a potentially improved safety profile. Precigen has advanced the UltraCAR-T platform to address the inhibitory tumor microenvironment by incorporating a novel mechanism for intrinsic checkpoint blockade without the need for complex and expensive gene editing techniques. UltraCAR-T investigational therapies are manufactured via Precigen's overnight manufacturing process using the proprietary UltraPorator ™electroporation system at the medical center and administered to patients only one day following gene transfer. The overnight UltraCAR-T manufacturing process does not use viral vectors and does not require *ex vivo* activation and expansion of T cells, potentially addressing major limitations of current T cell therapies.

AdenoVerse ™ Immunotherapy
Precigen's AdenoVerse immunotherapy platform utilizes a library of proprietary adenovectors for the efficient gene delivery of therapeutic effectors, immunomodulators, and vaccine antigens designed to modulate the immune system. Precigen's gorilla adenovectors, part of the AdenoVerse library, have potentially superior performance characteristics as compared to current competition. AdenoVerse immunotherapies have been shown to generate high-level and durable antigen-specific neutralizing antibodies and effector T cell immune responses as well as an ability to boost these antibody and T cell responses via repeat administration. Superior performance characteristics and high yield manufacturing of AdenoVerse vectors combined with UltraVector® technology allows Precigen to engineer cutting-edge investigational gene therapies to treat complex diseases.

UltraPorator ™
The UltraPorator system is an exclusive device and proprietary software solution for the scale-up of rapid and cost-effective manufacturing of UltraCAR-T therapies and potentially represents a major advancement over current electroporation devices by significantly reducing the processing time and contamination risk. The UltraPorator device is a high-throughput, semi-closed electroporation system for modifying T cells using Precigen's proprietary non-viral gene transfer technology. UltraPorator is being utilized for clinical manufacturing of Precigen's investigational UltraCAR-T therapies in compliance with current good manufacturing practices.

ActoBiotics ™
The ActoBiotics platform is precisely tailored for specific disease modification with the potential for superior efficacy and safety via local delivery directly to the relevant tissue. ActoBiotics are targeted, microbe-based, and specifically designed agents that express and locally deliver potential disease-modifying therapeutics at disease sites including the intestine, the mouth and the nasopharynx to treat a range of disorders.

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Precigen, UltraCAR-T, AdenoVerse, UltraVector, UltraPorator, ActoBiotics and Advancing Medicine with Precision are trademarks of Precigen and/or its affiliates. Other names may be trademarks of their respective owners.

Cautionary Statement Regarding Forward-Looking Statements
Some of the statements made in this press release are forward-looking statements. These forward-looking statements are based upon the Company's current expectations and projections about future events and generally relate to plans, objectives, and expectations for the development of the Company's business, including the timing and progress of preclinical studies, clinical trials, discovery programs and related milestones, the promise of the Company's portfolio of therapies, and in particular its CAR-T and AdenoVerse therapies. Although management believes that the plans and objectives reflected in or suggested by these forward-looking statements are reasonable, all forward-looking statements involve risks and uncertainties, including the possibility that the timeline for the Company's clinical trials might be impacted by the COVID-19 pandemic, and actual future results may be materially different from the plans, objectives and expectations expressed in this press release. The Company has no obligation to provide any updates to these forward-looking statements even if its expectations change. All forward-looking statements are expressly qualified in their entirety by this cautionary statement. For further information on potential risks and uncertainties, and other important factors, any of which could cause the Company's actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in the Company's most recent Annual Report on Form 10-K and subsequent reports filed with the Securities and Exchange Commission.

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